IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of Martin Roland JENSEN et al

Serial No. 09/060,294

Filed: April 15, 1998

MODIFIED TNF $\alpha$  MOLECULES, DNA ENCODING SUCH AND For:

VACCINES COMPRISING SUCH MODIFIED TNF $\alpha$  AND DNA



Examiner Romeo

Group Art Unit 1646

## RESPONSE

Asst. Commissioner of Patents Washington, D.C. 20231

Sir:

This is in response to the Office Action mailed October 1, 1999.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-28, 32, 40-45 and 47, drawn to a modified I.  $TNF\alpha$  molecule and DNA encoding same.
- Claims 29-31 and 46, drawn to a  $TNF\alpha$  vaccine comprising a DNA molecule encoding a modified  $TNF\alpha$ molecule.
- III. Claims 33, 34, 35, 36, 37 and 49 drawn to an in vitro diagnostic use of antibodies to a modified  $\mathtt{TNF}\alpha$ molecule.
- Claim 38, drawn to a method of treatment comprising IV. administering a modified TNF $\alpha$  molecule.



- V. Claim 39, drawn to a use of a modified  $TNF\alpha$  molecule for the manufacture of a medicament.
- VI. Claim 48, drawn to an  $in\ vivo$  diagnostic use of antibodies to a modified TNF $\alpha$  molecule.

In response to the restriction, applicants elect Group I, namely, claims 1-28, 32, 40-45 and 47 with traverse.

The Examiner states Inventions I and IV are related as product and process of use and are distinct because the polypeptide can be used in the method of Invention V. The Examiner then states Inventions I and V are related as product and process of use and are distinct because the polypeptide can be used in the method of Invention IV.

Group I is directed to a modified TNFα molecule. Group V is directed to a method for preparing a medicament from Group I. Group IV is directed to a method for the administration of Group I. While it is patently clearly that the polypeptide can be used in both of the methods of Groups IV and V, this begs the issue of distinctness. In fact, it demonstrates the lack of distinctiveness. In essence, Group I is the product, Group V is a method of making a medicament from the product, and Group IV is a method of administering the product for the same diseases for which the medicament is made. Thus, it is respectfully submitted that at least Groups I, IV and V should be examined together.

In view of the foregoing, early action on the merits is respectfully requested.

The Commissioner is hereby authorized to charge any fees due in connection with the filing of the present Response to Deposit Account 06-1358.



Respectfully submitted,

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By

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